

REMARKS

Reconsideration of claims 1, 6, 7-11, 15-17, 20, 22 and 25-28, and new claim 47, is respectfully requested. Claims 2-5, 12-14, 18, 19, 21 and 23 are canceled by this Amendment. Claims 1, 6-8, 10, 11, 20 and 22 are amended by this Amendment. Amended claim 1 includes the language of canceled claims 2, 5, 18, 19 and 21.

In response to the Restriction, Applicants elected the invention of Group I (claims 1-28) and elected hyaluronic acid as the representative viscoelastic polymer. Applicants submit that claims 18-22 are inclusive of the elected species as the claims are directed to a mixture containing both hyaluronic acid and hydroxypropylmethyl cellulose. In other words, claim 1 is amended to include the elected species as well as another viscoelastic polymer. This mixture is also recited in new claim 47.

The Official Action dated June 6, 2008 states that claims 18-22 are withdrawn pursuant to 37 CFR 1.142(b) as being directed to a nonelected invention. "The examiner should clearly set forth in the Office action the reasons why the claims withdrawn from consideration are not readable on the elected invention." MPEP 821.

Applicants respectfully request the examiner to reconsider the examination of these claims because each claim is inclusive of the previously elected species, hyaluronic acid and hexahydric alcohol. Applicant has amended the claims to a mixture comprising the elected hyaluronic acid with hydroxypropylmethyl cellulose, and the hexahydric alcohol. Accordingly, Applicants request reexamination of the amended claims as belonging to the elected invention.

The rejection of claims 12 and 14 under 35 USC 112, first paragraph is moot following the cancellation of these claims.

The rejection of claim 11 under 35 USC 112, second paragraph is respectfully traversed with respect to amended claim 11. Support for amended claim 11 is found on pages 15 and 16, which describe the colorimetric test for neutralizing the Fenton reaction with 2-deoxy-D-ribose. The described test allows one to determine the percentage of quenching potential for the claimed compositions. Claims are to be construed in light of the description provided in

the application. In this case, there is sufficient description in accordance with section 112 that allows one of ordinary skill to determine the quenching potential of a prepared solution.

The rejection of claims 1, 10-14, 23 and 25-28 under 35 USC 103(a) as obvious over WO 95/07085 (the '085 Application) in view of Stone (US 6,231,608) is respectively traversed with respect to the amended claims.

The '085 Application describes an ophthalmic viscoelastic composition comprising hyaluronic acid and its derivatives, hydroxypropylmethyl cellulose and mixtures thereof. There is no teaching or suggestion in the '085 Application of adding either a hexahydric alcohol or tris[hydroxymethyl]aminomethane (Tris).

Stone describes a soft (cartilage) or bone tissue xenograft that is chemically treated to minimize the immunogenic response to the foreign implanted tissue. In particular, Stone describes one embodiment in which the xenograft is "exposed to a chemical agent to tan or crosslink the proteins" within the xenograft. See, column 11, lines 36- 63. One suitable crosslinking agent is glutaraldehyde which is prepared in a buffered Tris solution. The sole purpose of chemically treating the xenograft is to minimize the immunogenic response a patient may have to the foreign tissue. Stone also describes the use of enzymes (glycosidases) to digest carbohydrate groups that may exist on cells at the surface of the xenograft. This treatment is said to kill the surface cells, which, if living, could also provoke an immunogenic response in the patient.

Applicants submit that there is no teaching or suggestion in Stone to use Tris in an ophthalmic viscoelastic composition and are somewhat puzzled by the proposed combination of cited references, and ask why one of ordinary skill in developing a viscoelastic composition would even look to Stone. First, Stone only mentions the use of a buffer in the presence of a crosslinking agent to chemically modify the xenograft, and without the crosslink agent there is no need for the described buffer. Second, Stone does not describe the use of a buffer with the enzyme (glycosidase) treatment as stated in the rejection. The buffer is only used with the crosslink agent.

Applicants respectfully submit that a proper rejection under section 103 requires more than just locating an element of a claim, and without more, combining that identified element with other claim elements identified in one or more other references. This is true even

following the holding in *KSR International*. For the reasons stated, Applicants respectfully disagree with the examiner's legal conclusion that "[o]ne of ordinary skill in the art would look to other compositions [i.e., the compositions described in Stone] to find a bufferant", particularly Tris, just because the primary reference mentions the use of a buffer. The examiner's reliance on Stone is misplaced and improper.

The rejection of claims 1, 3-8, 10-14 and 25-28 under 35 USC 103(a) as obvious over Chen et al. (US 6,761,903) in view of Stone is respectively traversed with respect to the amended claims for the same reasons why it was improper for the examiner to combine Stone with the '085 Application. Again, the holding in *KSR International* does not stand for the proposition that the mere identification of known elements in different references without more is sufficient reason for proposing the combination of those the references. More importantly, mere identification of known elements in references is not the test for obviousness under section 103. If otherwise, there would be no further inventions, no patents and no need for a patent office. This is particularly true in the context of a chemical invention.

For example, the teaching of Chen is directed to a pharmaceutical composition that includes a triglyceride (an oil), a polysaccharide drug and a surfactant. The surfactant is used to form a stable dispersion in an aqueous/triglyceride formulation, which is said to improve the delivery of the drug. In support of the rejection, the examiner indentifies each of the components of the claimed ophthalmic composition. Let us look at each of those listed components as described by Chen.

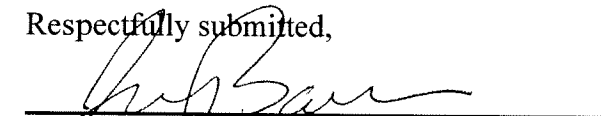
First, Chen lists eight (8) different types of polysaccharide drugs, one of which are the glycosaminoglycans. Hyaluronic acid is one of five glycosaminoglycans listed (claims 36-38). Second, Chen states that the triglyceride/surfactant formulations can also include a solubilizer (claim 51). The list of different solubilizers include "alcohols, polyols, amides, esters, propylene glycol ethers and mixtures thereof" (claim 52). Chen then lists twenty (20) or so different species and sub-genus of alcohols and polyols, two of which include sorbitol and mannitol. Third, Chen states that the triglyceride/surfactant formulations can also include "at least one additive" (claim 60). Chen lists a total of seventeen (17) different genus of additives, one of which is a bufferant.

The rejection improperly relies on a reference with virtually hundreds of different components that can be used to prepare a triglyceride/surfactant formulation. From this non-ending list, the examiner merely identifies hyaluronic acid, sorbitol or mannitol, and a bufferant. Why or how does the examiner select these particular components to arrive at the claimed composition out of the several thousand other compositions described in Chen? The only explanation is that the examiner has used the Applicants own invention as a guide to make such selections. That process is not a proper means by which a proper case of *prima facie* obviousness can be presented. Accordingly, Applicants respectfully request that the rejection as to the amended claims be withdrawn.

The rejections under section 103 as to claims 2, 9 and 23 are moot in light of the cancelation of claim 2 and the amendments made to claims 9 and 13. Moreover, Gohzu and Wohlrab do not overcome the deficiencies in the primary and secondary references for the reason already stated.

Reconsideration of this application is respectfully requested in view of the foregoing Amendment

Respectfully submitted,



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